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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,507	TERRAGNO ET AL.	
	Examiner	Art Unit	
	FELICIA C. KING	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 December 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-17, 19-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-17, 19-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>12/1/06</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Line 3 of claim 1 recites bacterial concentration "between 5.1010 and 5.1011 ufc/ml". Examiner has interpreted this portion of the claim as meaning "between 5×10^{10} and 5×10^{11} cfu/ml". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1: The term "more resistant" in claim 1 is a relative term which renders the claim indefinite. The term "more resistant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-17, and 19-23 are therefore rejected by their dependency on claim 1.

Further regarding Claim 4: Claim 4 recites the limitation "the bacteria both characteristics i) and ii)." in line 2 of claim 4. There is insufficient antecedent basis for this limitation in the claim. Examiner has interpreted this claim as dependent upon Claim 3 however, appropriate correction is required.

Further regarding Claim 5: Claim 5 recites the limitation "the food product" in line two of claim 5. There is insufficient antecedent basis for this limitation in the claim.

Further regarding Claim 7: the phrase "capable of being obtained" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Further regarding Claim 13: The term "primarily between" in claim 13 is a relative term which renders the claim indefinite. The term "primarily between" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Further regarding Claim 22: Claim 22 recites the limitation "the production line" in line 4 of claim 22. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 1- 6, 8, 9, 14, 15, 17, 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308) and Yang et al. (US 6,306,638).**

Regarding Claims 1 and 2: Bengtsson-Riveros discloses liquid bacteria concentrates [pg. 2, para 0020; 0025] having viable bacteria at a concentration of 1.5×10^8 to 5×10^{11} cfu/ml[pg. 3, para 0031]; and further discloses where the bacteria are species selected from Lactobacillus, Bifidobacterium, Streptococcus, Lactococcus [pg. 3, 0033]; and also discloses the bacteria that can be concentrated via filtration methods known in that art [pg. 4, para 0051], but does not explicitly disclose where the bacteria are adapted and more resistant to various physiochemical stresses. However, Yang discloses adaptation of Bifidobacterium that are to be used in food products, where the bacteria have been adapted to have increased tolerance to gastric acid and oxygen [col. 9, lines 25-35; 41-46].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang before him or her to modify the bacteria of Bengtsson-Riveros to include adapted bacteria because this would have allowed for the selection of bacteria having the ability to maintain its viability during periods of extended storage and to allow the bacteria to survive passage through the stomach (gastric acid) in order to provide its beneficial effect by maintaining healthy microflora in the intestines [col. 1, lines 24-32, col. 9, lines 25-46].

Regarding Claims 3 and 4: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the bacteria have a survival rate of above 80% even after 90 days of storage at 20°C with a food product that is children's breakfast cereal [pg. 7, Table 16]. The 80% figure was computed from the 90 day viable cfu count versus the starting cfu count [pg.7, Table 16]. Although Bengtsson-Riveros does not explicitly disclose the pH of the cereal being between 3 and 7, it is well known in the art that cereals have a pH between 5 and 6. Further Bengtsson-Riveros discloses in invitro testing of bacteria showing the ability to withstand gastric and bile acids [pg.2 para. 0027].

Regarding Claim 5: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where liquid bacteria concentrate can be added to beverages [pg.4, para 0049].

Regarding Claim 6: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the liquid bacteria concentrate is viable up to 1 year [pg.4, para 0049].

Although Bengtsson-Riveros does not disclose the viability of the bacteria being between 4 to 6 weeks it does disclose that the bacteria are viable for up to 1 year (up to 52 weeks) thereby encompassing and surpassing the 4 to 6 week requirement of the claim, therefore, one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Bengtsson-Riveros overlap the instantly claimed proportions and therefore are considered to establish a *prima facie* case of obviousness. *In re Malagari* 182 USPQ 549,553.

Regarding Claims 8 and 9: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above but does not explicitly disclose where the bacteria are adapted based upon

parameters of the bacteria or the bacterial culture medium. However, Yang discloses where parameters for determining adaptation are based upon pH tolerance and oxygen tolerance of the bacteria [col.7, lines 40-44].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang before him or her to measure the adaptation of the bacteria based on pH in order to determine whether the bacteria used in the food product would have been able to withstand an acidic environment in order for the bacteria to be useful as probiotics.

Regarding Claim 14: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above but does not explicitly disclose where the pH of the concentrate is between 3 and 6. However, Yang discloses where the pH of medium for storage of bacteria concentrate is 6.2 to 6.5 [col. 9, lines 64-67; col. 10, lines 1-14] and further discloses where the pH of the culturing medium could be from 5 to 9 [col. 10, lines 46-50].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang before him or her to include the concentrate at the pH as disclosed in Yang in order to maintain the bacteria in a slightly acidic environment to maintain a favorable environment for bacteria that have been adapted for a more acidic environment.

Further regarding the pH of the storage medium, although Yang does not disclose where the pH is between 3 and 6 as in the instant claim, the ranges disclosed are substantially close to that of the instant claims, one of ordinary skill would have expected compositions that are in such close proportions to those in prior art to be *prima facie* obvious and to have same properties. *Titanium Metals Corp.*, 227 USPQ 773 (CAFC 1985).

Further regarding the pH of the culture medium, although Yang does not disclose where the pH is between 3 and 6, one having ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Yang overlap the instantly claimed proportions and therefore are considered to establish a *prima facie* case of obviousness. *In re Malagari* 182 USPQ 549,553.

Regarding Claim 15: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses freezing them after packaging [pg. 2, para 0020, pg. 3, para 0041], where the instant claim recites preserving at temperature between -50°C and 4°C after packaging. Although Bengtsson-Riveros, does not explicitly disclose preserving at temperatures between -50°C and 4°C after packaging, it is well known in the art that freezing occurs at temperatures from 0°C and below and that at such temperatures products that are subject to degradation are preserved, therefore the recitation of the freezing the packaged material satisfies the limitations of the claim.

Regarding Claims 17, 20, 21: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the liquid concentrate is added to food additives and food products, and beverages such a cereal powders, powdered milk, chocolate, cereals, and beverages [pg. 4, para 0049].

Regarding Claim 22: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the bacteria can be directly added to the consumable product and stored with the consumable product [pg. 2, para 0024]and further discloses adding probiotics to the consumable product before packaging the product [pg. 3, para 0040].

Regarding Claim 23: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the bacteria can be applied to the consumable product by spraying [pg. 2 , para 0020]. Although Bengtsson-Riveros does not explicitly state the liquid

concentrate is added by pumping, spraying onto the consumable product involves a pumping action and therefore satisfies the limitation of the claim.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a spraying device because it involves pumping action and is commonly used to distribute liquid products that will be applied directly to food and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin* 125 USPQ 416

7. **Claims 7, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308) and Yang et al. (US 6,306,638) as applied to claims 1 and 8 above, and in further view of Hayakawa et al. (Applicant's NPL).**

Regarding Claim 7: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the concentrate is made by growing the bacteria in a liquid medium [pg.1, para 0014] and concentrating the bacteria by filtration but does not explicitly disclose where the bacteria are adapted, washed and concentrated by tangential microfiltration. However Yang discloses bacterial adaptation as discussed above. However, Hayakawa discloses where Lactobacilli are grown in culture medium, and where a cross flow filtration system (tangential microfiltration) is used to wash and feed bacteria with fresh medium and to concentrate the bacteria in order to get high density cultivation of bacteria [pg 404-405 **Culture**].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang and Hayakawa before him or her to modify the culture in Bengtsson-Riveros to include a continuous culturing process where the bacteria are washed/fed fresh medium and concentrated using cross-flow filtration (tangential microfiltration) because it avoids plugging of the membrane as in traditional filtration systems [Hayakawa, pg 404

Abstract] and allows for the maintenance of preferred pH ranges because of the lack of lactic acid build up from the proliferating cells, and increases the amount of cells cultivated because an environment favorable for growth is maintained [Hayakawa, pg 404 Abstract].

Regarding Claims 10 and 11: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above but does not disclose where the parameter of the culture medium is pH and the adaptation step is performed by reducing the pH by natural acidification. However, Yang discloses bacterial adaptation as discussed above but regulates the pH by adding acids to the medium. However, Hayakawa discloses bacteria that are maintained via cross-flow filtration in a particular culture medium where the pH is maintained based on the amount of glucose present in the culture medium and the amount of pH lowering lactic acid being produced [pg. 407, and Fig. 7].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang and Hayakawa before him or her to modify the method of adaptation as disclosed in Yang to include the adaptation using natural acidification as disclosed in Hayakawa in order to maintain the desired pH within a sterile environment so that the concentrated bacteria can be directly added to food products or directly packaged for later addition to food products.

8. **Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308) and of Yang et al. (US 6,306,638) as applied to Claims 1 and 8 above, and in further view of SCKCEN “Physiological Approach to Monitor Space and Stress Response in Bacteria” 2003.**

Regarding Claim 12: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above but does not disclose where the parameter is bacteria size. Yang discloses bacterial adaptation

as discussed above. However, SCK·CEN discloses that physiological stresses such as pH can affect the size of bacteria [col. 1, Objectives].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros and Yang and SCK·CEN before him or her to modify the method of adaptation as disclosed in Yang to include the adaptation using detection of bacteria shape as discussed in SCK·CEN as it has been disclosed that exposing bacteria to stress can cause a change in the size of the bacteria. Further this reaction (size reduction) to stress can be an indicator as to whether the bacteria would react favorably under desirable conditions.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308), Yang et al. (US 6,306,638), and SCK·CEN “Physiological Approach to Monitor Space and Stress Response in Bacteria” 2003 as applied to claim 12 above, and in further view of McDaniel (US 2004/0175407).

Regarding Claim 13: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above but does not disclose where the lengths of the bacteria are between 0.1 to 10 μm . Yang discloses bacterial adaptation as discussed above. SCK·CEN discloses that physiological stresses such as pH can affect the size of bacteria as discussed above. However, McDaniel discloses where species of *Lactobacillus* have lengths in the range of 1.0 -10 μm , species of *Bifidobacterium* have lengths in a range of 1.5 - 8.0 μm , species of *Streptococcus* have lengths in a range of 0.5 – 2.0 μm , species of *Lactococcus* lengths in the range of 0.5 -1.5 μm [pg 21, Table 3].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros, Yang, SCK·CEN, and McDaniel before him or her to include bacteria having lengths of between 0.1 to 10 μm since these are physical

characteristics exhibited by the preferred bacteria of the invention which are disclosed in Bengtsson-Riveros (Lactobacillus, Bifidobacterium, Streptococcus, Lactococcus [pg. 3, 0033]).

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308) and Yang et al. (US 6,306,638) as applied to claims 1 and 15 above and in further view of Rinfret et al. (US 3,228,838).

Regarding Claim 16: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses thawing them after freezing [pg. 2, para 0020, pg. 3, para 0041], but does not explicitly disclose reheating to a temperature between 25°C and 45°C. Yang discloses adaptation as discussed above. However, Rinfret discloses preserving biological substances such as blood, bacteria, yeast, beverages from degradation by freezing and then thawing at 37 °C [col. 1, lines 16-20; col. 7, lines 13-37].

At the time of the invention, it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros, Yang and Rinfret before him or her to thaw the bacteria at 37 °C because it would bring the bacteria to a temperature that is favorable to maintaining their viability [Rinfret, col. 3, lines 16-19].

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson-Riveros et al. (US 2004/0115308) and Yang et al. (US 6,306,638) as applied to claim 1 above and in further view of Bensel (US 2,364,049).

Regarding Claim 19: Bengtsson-Riveros discloses liquid bacteria concentrates as discussed above and further discloses where the liquid concentrate is packaged in a hermetically sealed bag in order to preserve the product and to maintain the shelf life of the product [pg. 3, para 0040], therefore it can be inferred that given this description, the product is sterile because of the maintenance of shelf life and water activity and that the bag is flexible since flexibility is a physical

characteristic of bags however these are not explicitly disclosed. Yang discloses adaptation as discussed above. However, Bensel discloses packaging perishable items by sterilizing them and loading into flexible heat sealable bags [pg. 2, lines 53-58].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Bengtsson-Riveros, Yang and Bensel before him or her to package the liquid concentrate in flexible hermetically sealed, sterile packaging because it would prevent the degradation of the liquid concentrate (maintain the shelf life) and prevent contamination with undesirable pathogenic bacteria or bacteria that has not been adapted for use as probiotics.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./
Examiner, Art Unit 1794

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